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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,400	09/20/2005	Kenji Sato	HOP03167US0	9280

26271 7590 04/27/2007
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EXAMINER

GUSSOW, ANNE

ART UNIT	PAPER NUMBER
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1643

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/574,400		SATO ET AL.	
	Examiner		Art Unit	
	Anne M. Gussow		1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 3, 8 and 9 have been cancelled.
Claims 1, 2, 4, and 10-11 have been amended.
Claim 12 has been added.
2. Claims 1, 2, 4-7, and 10-12 are under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
4. The following Office Action contains NEW GROUNDS of rejections.

Objections Withdrawn

5. The objection to the specification has been withdrawn in view of applicant's amendments.

Rejections Withdrawn

6. The rejection of claims 1-11 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment to the claims.
7. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's cancellation of the claim.
8. The rejection of claim 11 under 35 U.S.C. 102(b), is withdrawn in view of applicant's arguments.

Rejections Maintained

9. The rejection of claims 1-11, and the newly added claim 12 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

Applicant's arguments filed March 14, 2007 have been carefully considered by they are deemed not to be persuasive. The response states, "Claim 11 has been amended to remove the prior reference to any one of claims 1-7. Claim 1 has been rewritten for clarity, including positively reciting the source material as a limitation" (see response page 8). In response to this argument, the limitation in claims 1 and 11 "has a molecular weight of 500kDa or more" includes a broad genus of proteins obtainable by the extraction method of claim 11. While the amended claims clarify the method of obtaining the composition, there is still insufficient written description as to the composition of the extract having 500kDa molecular weight or more. As such the rejection is maintained.

10. The rejection of claims 1-10, and the newly added claim 12 under 35 U.S.C. 102(a), is maintained.

Applicant's arguments filed March 14, 2007 have been carefully considered but they are deemed not to be persuasive. The response states that "the main component of the claimed composition has a molecular weight of 500 kDa or greater and several other recited biophysical characteristics. This is compared to the crude shark extract of Murata which is a complex heterogeneous mix of proteins." (see response page 9). In

response to this argument, the claims still encompass the extract of Murata because the water extract of Murata was precipitated with ethanol and the precipitate was freeze-dried to yield SCE (see Murata translation page 6, Chemicals). Thus, the composition of Murata contains the 500kD or more molecular weight proteins of the instant composition. As such the rejection is maintained.

Regarding claim 12, Claim 12 is drafted in the product-by-process format. The references do not describe the production of the molecule using the methods identical to that is recited in claim 11. However, the recitation of a process limitation in claim 11 is not viewed as positively limiting the claimed product absent a showing that the process of making recited in claim 11 imparts a novel or unexpected property to the claimed product, as it is assumed that equivalent products are obtainable by multiple routes. The burden is placed upon the applicants to establish a patentable distinction between the claimed and references products.

Applicant is reminded that when the claim is directed to a product, the preamble is generally nonlimiting if the body of the claim is directed to an old composition and the preamble merely recites a property inherent in the old composition. [*Kropa v. Robie*, 88 USPQ 478, 480 - 81 (CCPA 1951); see also MPEP 2111.02.

The method in which the compositions were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the

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claim is unpatentable even though the prior product was made by a different process.”

In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113.

11. The rejection of claims 1-11 and newly added claim 12 under 35 U.S.C. 103(a), is maintained.

Applicant's arguments filed March 14, 2007 have been carefully considered but they are deemed not to be persuasive. The response states that “WO03/068249 A1 is not available as a 102(b) reference and Murata is distinguished by the claim amendments” (see response page 9). In response to this argument, the WO03/068249 A1 reference is available as 102(e) art and is therefore available for the 103(a) rejection. Additionally, the amendments to the claims have not distinguished the instant composition from the cartilage extract of Murata as set forth under 102(a) above. Regarding the amendment to claim 11, Kralovec teach gel filtration of their extract composition (see page 12 lines 9-13). Regarding claim 12, see the arguments under 35 U.S.C. 102(a) above. Therefore, it would have been obvious to make the composition of Murata with a particle size of Kralovec (WO 03/068249) and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Kralovec, et al. (WO 2003/068249 A1).

The claim recites a method of producing a proteoglycan extract from shark cartilage by pulverizing the cartilage to an average particle diameter of 100 μm or less, adding water, separating the aqueous phase, precipitating with an alcohol, and gel filtration purifying the precipitate.

Kralovec, et al. teach a method of isolating a proteoglycan extract from a shark by pulverizing the sample and adding water, with a number of possible subsequent steps one of which is separating the aqueous phase and precipitation with an alcohol (pages 9-13, particularly page 12 lines 14-20 and Method C pages 20-21). Kralovec, et al. teach pulverizing the cartilage sample to an average particle size of 35 μm (page 18 lines 22-23). Kralovec, et al. also teach gel filtration purification of the precipitate (page 12 lines 11-13).

Since the method steps of claim 11 are included in the method of Kralovec, et al., all the limitations of the claim have been met.

Conclusion

14. No claims are allowed.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow, Ph.D.

April 13, 2007



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER